APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/816,110	04/01/2004	Huwei Tan	0010.0010US1	8501

29127   7590   07/16/2007
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EXAMINER
FERNANDEZ, KATHERINE L

ART UNIT	PAPER NUMBER
3768	

MAIL DATE	DELIVERY MODE
07/16/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)
Office Action Summary	10/816,110	TAN, HUWEI
	Examiner	**Art Unit**	
	Katherine L. Fernandez	3768	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>3</u> MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.
- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on <u>26 May 2006</u>.

2a)☐ This action is **FINAL**.   2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) <u>1-53</u> is/are pending in the application.

    4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) <u>1-53</u> is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on <u>20 May 2004</u> is/are: a)☒ accepted or b)☐ objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

    a)☐ All b)☐ Some * c)☐ None of:

      1.☐ Certified copies of the priority documents have been received.

      2.☐ Certified copies of the priority documents have been received in Application No. _____.

      3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

    * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>5/26/2006; 8/5/2005; 9/15/2004</u>.

4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.

5) ☐ Notice of Informal Patent Application

6) ☐ Other: _____.

Information Disclosure Statement

1.   The Information Disclosure Statements filed on September 15, 2004, August 5,

2005 and May 26, 2006 are acknowledged. The Information Disclosure Statements

meet the requirements of 37 C.F.R. 1.97 and 1.98 and therefore the references therein

have been considered.

Claim Rejections - 35 USC § 103

2.   The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all

obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set
> forth in section 102 of this title, if the differences between the subject matter sought to be patented and
> the prior art are such that the subject matter as a whole would have been obvious at the time the
> invention was made to a person having ordinary skill in the art to which said subject matter pertains.
> Patentability shall not be negatived by the manner in which the invention was made.

3.   Claims 1-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over

Marshik-Geurts et al. (US Pub. No. 2004/0024298) in view of Tan et al. ("Multivariate

calibration of spectral data using dual-domain regression analysis", 2003) as cited by

applicant.

Marshik-Geurts et al. disclose a method for optically analyzing blood vessel

walls, the method comprising of a detector system for receiving optical signals from the

vessel walls (pg 4, paragraph [0047]; pg. 5, paragraph [0053], [0061]-[0063]); a

spectrometer for resolving a spectrum of the optical signals to generate spectral data

(pg. 5, paragraphs [0062]-[0063], paragraph [0067]; and an analyzer for transforming

the spectral data and using the transformed data to analyze the vessel walls (pg. 5,

paragraph [0067]; pg. 6, paragraphs [0073]). An optical source that generates near

infrared light illuminates the blood vessel walls (pg.5, paragraphs [0053]-[0058]).

Further, the step of receiving the optical signals comprises detecting returning radiation

to a catheter head (pg. 5, paragraph [0060]). The analysis of the vessel walls

comprises determining whether the blood vessel walls are comprised of vulnerable or

non-vulnerable plaques, as well as measuring vulnerability for a risk of heart attack (pg.

5-6, paragraph [0067]; pg. 1, paragraph [0008]). The transforming step is performed as

a preprocessing step, before a discrimination algorithm is applied (pg. 6, paragraphs

[0070]-[0073]). The preprocessing removes, filters-out, or deemphasizes the

contribution to the intervening unwanted spectral signatures (pg. 6, paragraph [0071]).

Marshik-Geurts further disclose that a generalized least squares method is used as an

"unwanted signal filter" and is a weight strategy (pg. 7, paragraph [0079], pg. 8,

paragraph [0100]). The step of applying the weight strategy (i.e. generalized least

squares method) comprises applying the receiver operating characteristic-area under

curve analysis (pg. 12, paragraph [0142], pg. 13, paragraph [0152]). By examining the

plot of the receiver operating characteristic-area under curve, the ability of the model to

separate two class groups can be assessed (pg. 12, paragraph [0142]). Although

Marshik-Geurts et al. do not specifically disclose that a decision boundary (or surface)

can be set by applying the receiver operating characteristic-area under curve technique,

it would have been obvious to one of ordinary skill in the art to do so because the

technique indicates the ability of two classes to be separated from each other, as taught

by Marshik-Geurts et al. (pg. 12, paragraph [0143]). Furthermore, the step of applying

the weight strategy comprises applying optimization to maximize separation between

discrimination classes and to increase the prediction performance of vulnerability for a risk of heart attack (pg. 15, claim 9 and claim 34). Their method comprises applying a Mahalanobis classifier in their method of analyzing the vessel walls (pg. 9, paragraph [0109]). Marshik-Geurts also disclose that their method includes applying multivariate regression techniques (pg. 15, claim 23). They further disclose that the discrimination model can be a single domain model (pg. 9, paragraph [0109]).

However, Marshik-Geurts et al. do not disclose that their method involves transforming the spectral data into dual-domain spectral data.

Tan et al. disclose the use of dual-domain regression analysis applied to spectral data (pg. 292, column 1, 2nd paragraph; pg. 292-295, Section 2). The dual-domain regression analysis comprises applying a wavelet prism (pg. 292, column 2, Section 2, 1st paragraph). Further, the step of transforming the spectral data into the dual-domain spectral data comprises applying a time-frequency transform and decomposition methods, optimized in response to analytes and interferants (pg. 292, column 2, 1st paragraph; pg. 297, column 1, 2nd paragraph; pg. 298, column 2, 2nd paragraph). Their discrimination model is a dual domain model (pg. 292, Section 2.1). Tan et al. disclose that aspects of the spectra, such as low-frequency components and noise, can be stripped out in some situations to reduce the complexity of multi-variate regression models (pg. 292, column 2, 2nd paragraph). Before transforming the spectral data into the dual domain spectral data, Tan et al. disclose that the NIR spectra of the samples are mean-centered (i.e. a preprocessing step is performed before transforming the spectral data into the dual domain spectral data) (pg. 292, column 2, 1st paragraph).

Further, they disclose that they perform dual-domain multivariate regression techniques to analyze the data (pg. 293-295, Section 2.2). The regression technique comprises applying a weight strategy (pg. 294, column 1, 3rd paragraph through column 2, 3rd paragraph, referring to the use of a weighted average regression vector). Cross-validation techniques are applied in the step of applying a weight strategy (pg. 294, column 1, 3rd paragraph through column 2, 1st paragraph). At the time of the invention, it would have been obvious to one of ordinary skill in the art to transform the spectral data into dual-domain spectral data in the method of Marshik-Geurts et al. The motivation for doing so would have been dual-domain spectral analysis has been shown to have improvements in prediction power, robustness, and model complexity as taught by Tan et al. (pg. 301, Section 5).

Conclusion

4.   Any inquiry concerning this communication or earlier communications from the examiner should be directed to Katherine L. Fernandez whose telephone number is (571)272-1957. The examiner can normally be reached on 8:30-5, Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni M. Mantis-Mercader can be reached on (571)272-4740. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only.

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you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

USPTO Customer Service Representative or access to the automated information

system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.